

Clinical Edit Criteria Proposal

Drug/Drug Class: Combunox® Tablets Clinical Edit

Date: November 16, 2005

Prepared for:

Prepared by: Missouri Medicaid

☒ **New Criteria**

☐ **Revision of Existing Criteria**

Executive Summary

Purpose: Ensure appropriate utilization and control of Combunox® (oxycodone and ibuprofen combination tablets).

Why was this Issue Selected: Combunox® is a branded drug product containing oxycodone and ibuprofen that is indicated for short-term relief of acute moderate to severe pain. Each Combunox tablet contains 5mg Oxycodone and 400mg Ibuprofen. The side effect profile for this product, including risk of abuse, gastrointestinal bleed, dizziness, and nausea, mirror the side effect profile for each individual ingredient.

The combination product is 30% more expensive than the MAC'd individual products filled separately.

Program-specific information:	Drug	Dosage Form	Cost per Dosage Form
	• Combunox®	5mg-400mg tab	\$1.5000 AWP

Setting & Population: All patients.

Type of Criteria:

☐ Increased risk of ADE

☒ Appropriate Indications

☒ Non-Preferred Agent

☐

Data Sources: ☒ Only administrative
databases

☐ Databases + Prescriber-
supplied

Setting & Population

- Drug for review: Combunox® (oxycodone and ibuprofen tablets)
- Age range: All ages
- Gender: Male and female

Approval Criteria

Patient is unable to take generic tablet due to:

- Documented ADE/ADR to individual ingredient generic tablet therapy, or
- Trial and failure of individual oxycodone and ibuprofen tablet therapy in the past 45 days.

Denial Criteria

- Failure to meet approval criteria.

References

1. Facts and Comparisons, p.798 - 806. 2005.
2. USPDI, Micromedex, 2005.
3. Forest Pharmaceuticals, Inc., "Combunox.com", St.Louis, MO. May 2005.

